



BUCR-020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: R. R. Burch et al.

: Art Unit: 1615

Serial No.: 09/245,625

: Examiner: T. Ware

Filed: Feb. 5, 1999

:

FOR: CHEMICALLY ACTIVE FIBER

:

COMPOSITIONS AS DELIVERY

:

SYSTEM FOR CHEMOTHERAPEUTIC

AGENTS, ESPECIALLY FOR

SUBSTANCES USEFUL IN DENTAL

HYGIENE

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10-15-01**APPELLANTS' BRIEF UNDER 37 C.F.R. § 1.192**

Box AF

Hon. Asst. Commissioner for Patents

Washington, DC 20231

This brief is in furtherance of the Notice of Appeal, filed August 6, 2001.

(1) REAL PARTY IN INTEREST

The real party in interest is Delta Dental Hygienics LLC, a corporation duly organized under and pursuant to the laws of the State of Louisiana, and having its principal place of business at 2514 Audubon Street, New Orleans, Louisiana 70125.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(3) STATUS OF CLAIMS

Claims 1-22 and 25-29 are pending in the application. Claims 23 and 24 have been cancelled. Claims 1-22 and 25-29, all the claims pending in the

application, are appealed.

Claims 1-22 and 25-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Burch, U.S. Pat. No. 5,433,266, in view of Hill, U.S. Pat. No. 5,098, 711.

(4) STATUS OF AMENDMENTS

An amendment to put the claims in better condition for appeal has been filed with this Appeal Brief. It is assumed that this amendment has been entered. The appended claims show the claims after entry of the amendment.

(5) SUMMARY OF THE INVENTION

The invention is an elastomeric fiber, useful as a dental floss, that comprises a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber. A preferred fiber is spandex fiber. A preferred chemotherapeutic agent is fluoride. Spandex has been shown to absorb over 2,000 ppm of fluoride. Methods for preparing the fiber are also claimed.

(6) ISSUES

1. Is appellants' invention unpatentable over a combination of two references when the combination of the two references does not produce the *prima facie* case because one of the references does not disclose or suggest what the Examiner alleges it does?

2. May an Examiner prevent an applicant from challenging his interpretation of a reference, and thus showing that a combination of references does not produce the *prima facie* case, by citing case law that allegedly holds that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references?

3. What is the meaning of the adjective "imbibed" and does it distinguish appellants claims from the disclosure of a reference in which materials are contained essentially in the interstitial spaces between the fibers of a dental floss?

(7) GROUPING OF CLAIMS

The claims do not all stand and fall together. They are grouped as follows:

Group I - Claims 1 and 10.

Group II - Claims 2, 3, and 11.

Group III - Claims 4, 20, and 21.

Group IV - Claims 5-9, 12, and 22.

Group V - Claims 14, 16, 17, and 19.

Group VI - Claims 13, 15, 18, and 25-29.

The significant limitations of each group of claims are discussed below.

(8) ARGUMENT

A. The Applied References

1. Burch, U.S. Pat. No. 5,433,266 ("Burch")

Burch discloses a dental hygiene product, and more particularly dental floss comprising a fiber having a core of a segmented polymer. The segments of the polymer are a combination of soft segments, preferably of polyether or polyester type, and of hard segments selected from a group consisting of polyurethane, polyamide, polyimide, and a mixture thereof. The content in hard segments is 5-40% of the polymer by weight. The dental floss of this invention is characterized by exceptionally robust elastic properties, which are necessary to ensure effective and efficient cleaning of teeth. Abstract.

Burch, an earlier patent by one of the inventors of the instant invention, generally discloses an elastomeric dental floss. The elastomeric dental floss of Burch is imbibed with a chemotherapeutic agent to produce the instant invention. The Examiner admits that Burch does not disclose impregnating the fiber with a chemotherapeutic agent. Paper 5, page 3, lines 13-14; paper 10, lines 23-24.

2. Hill, U.S. Pat. No. 5,098, 711 ("Hill")

Hill discloses a method of treating the oral cavity with a preparation released from dental floss. Hill, Abstract. The floss may include natural and/or synthetic fibers. Hill, column 12, lines 11-13. The floss may comprise one or more chemotherapeutic agents. Column 13, lines 49-53; column 15, lines 16-22.

The preparation released by the dental floss is "contained essentially in the interstitial spaces between the fibers of the floss." Hill, column 13, lines 60-61. Loading is achieved by introducing a substantially aqueous free hot- melt emulsion of the composition into the space around the opened fibers. Hill, column 6, lines 47-48, lines column 13, lines 63-66. The loaded floss opens up and flattens out during flossing, releasing the composition. Hill, column 13, line 67, to column 14, line 6.

3. Additional Reference Relied on by the Examiner, but not Made of Record

In addition to the references discussed above, the Examiner has relied on the following additional reference, which has not been made of record:

Merriam-Webster's' Collegiate Dictionary (10th edition) definition of "imbibed." According to the Examiner, the definition of "imbibed" is "to absorb or assimilate moisture, gas, light, or heat" Paper 10, page 5, lines 17-19.

B. The Examiner's Initial Positions

In an Advisory Action, the Examiner asserted that appellant's claims were

anticipated because (1) "[n]ylon is a polyvinyl polymer" and (2) "the instant specification discloses that nylon (which is disclosed by Hill) is an elastomeric polymer." Advisory Action, paper 7, page 2, lines 1-12. In their response, appellants specifically asked the Examiner to support these statements.

Despite appellants' express request, the Examiner did not provide support for either of these assertions. Although the Examiner did not repeat these assertions in the next communication, he did not specifically indicate that this was not longer his position. However, the Examiner has abandoned this position by his failure to support it when specifically requested to do so. Therefore, appellants' will not respond to these assertions unless the Examiner repeats them in his Reply Brief.

The Examiner also initially alleged both appellants and Hill used the same process to incorporate the active ingredients into the fibers. Paper 5, page 4, lines 9-11. This is incorrect. Appellants add the fiber to an aqueous solution or dispersion of a chemotherapeutic agent, such as a solution of fluoride. Hill introduces his composition into the space around the fibers using a substantially aqueous free hot-melt emulsion. Hill, column 6, lines 47-48; column 13, lines 63-66; claim 1, lines 20-21. The Examiner has also abandoned this position. It was not repeated in the most recent rejection. Paper 10.

C. Claims on Appeal

There are 27 claims on appeal. Claims 1-9 and 25-29 are drawn to an elastomeric fiber comprising a therapeutically effective amount of a chemotherapeutic agent imbibed in the fiber. The dependent claims recite additional limitations for the fiber and for the nature and amount of the a therapeutically effective amount of the chemotherapeutic agent . Claims 10-13 are drawn to an assembly that comprises the fiber. Claims 14-18 are product-by process claims drawn to a fluoride-containing fiber. Claims 19-20 are method claims drawn to a method for producing a fluoride-containing fiber. Claims 20-22 are method

claims drawn to a method for producing a fiber comprising a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber.

In the rejection, the Examiner has not distinguished between the individual claims, but has rejected the all claims as a group. For purposes of appeal, appellants have divided the claims into six groups. The significant limitations of each of group will be discussed below with respect to the rejection.

D. The Rejection

All the claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Burch in view of Hill. The rejection is summarized as follows:

[Hill] is relied on for teaching multiple stranded or filamented nylon dental floss loaded with chemotherapeutic agents such as penicillin, sodium fluoride, stannous fluoride, or chlorhexidine prepared by dipping the floss into an agitated bath containing the therapeutic agent.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of [Burch] and [Hill] with expectation of success, since both the floss of [Burch] and that of [Hill] utilize polymer fibers in the form of multiple strands or filaments, and the motivation that the antimicrobial agents of [Hill] would impart antimicrobial properties of the fibers [Burch] thereby providing an effective means to deliver these antimicrobial agents to the oral cavity or gingiva and that such a floss would accommodate and clean the spacings of different dimensions between teeth while maintaining strength.

Paper 10, page 3, lines 1-12.

E. Appellants Response to the Rejection

1. Response with Respect to the Claims of Group I and All the Other Pending Claims

Group I consists of claims 1 and 10. The rest of the claims have limitations similar to those of claims 1 and 10. Therefore, the following also applies to all the claims, not just the claims of Group I.

(a) The Examiner has not made the *prima facie* case.

Combination of Burch and Hill does not produce appellants' invention.

The Examiner has not made the *prima facie* case. The combination of Burch and Hill does not produce appellants' invention. In particular, Hill does not teach imbining or absorbing, a chemotherapeutic agent into a fiber.

In Hill's method, the compositions released by the dental floss are loaded in interstitial spaces between the fibers of a multi-strand floss. With respect to the location of the preparations in the dental floss, Hill states:

A review of the construction of the preferred floss used in the method of the present invention shows that the compositions employed are contained essentially in the interstitial spaces between the fibers of the floss with minimum composition on the outer surface of the floss.

Hill, column 13, lines 58-62 (emphasis added).

Hill also states:

The unique construction of the floss and loading of cleaners, active ingredients and conditioners in the space around each of the nylon fibers allows loading of these substances from 10 to over 100% by weight of the floss.

Hill, column 5, lines 17-21 (emphasis added); *see also*, column 19, line 39, to column 20, line 11; and claim 1, lines 22-26.

Hill discloses a dental floss in which the composition released by the floss is loaded in the interstitial spaces between the fibers of a dental floss. In the invention recited in appellants' claims, a therapeutically effective amount of a chemotherapeutic agent is imbibed in the fiber.

The Examiner admits that Burch does not disclose impregnating the fiber with a chemotherapeutic agent. Paper 5, page 3, lines 13-14; paper 10, lines 23-24. Hill does not overcome this deficiency. Hill discloses loading a composition into the interstitial spaces between the fibers of a dental floss. Consequently, combination of the references in the manner indicated by the Office does not produce appellants' invention.

To make the *prima facie* case, the "reference (or references when combined) must teach or suggest all of the claim limitations." MPEP 4142 (case citations omitted) (emphasis added). The Examiner has admitted that this is the law. Paper 10, page 4, lines 12-13.

The Examiner has not made the *prima facie* case. The rejection of claims 1-22 and 25-29 as unpatentable over the combination of Burch and Hill should be reversed.¹

(b) There is no reasonable expectation of success from the combination of Burch and Hill

Assuming for the sake of argument that Hill discloses what the Examiner alleges it does (which it does not), there is no reasonable expectation of success

¹ In response, the Examiner has alleged that appellants are "attacking references individually" and that "imbibed does not distinguish how the fiber is loaded with agent, merely that it is loaded with agent." These issues are discussed below.

from the combination of Burch and Hill.

Burch discloses an elastomeric dental floss. Burch, Title. Hill discloses dental floss of "natural and/or synthetic fibers and mixtures thereof including cotton, silk, polyester and nylon." Hill, column, 12, lines 11-13. None of the materials disclosed by Hill are elastomers.²

As is well known to those skilled in the art, the physical properties of elastomeric polymers are different than those crystalline polymers, such as nylon. Thus, the person of ordinary skill in art would have no reasonable expectation of success in substituting the elastomeric polymer of Burch for the non-elastomeric polymers of Hill. As best, the combination is "obvious to try." The Federal Circuit has "consistently held that 'obvious to try' is not to be equated with obviousness under 35 U.S.C. § 103." *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 U.S.P.Q.2d 1923, 1928 (Fed.Cir. 1990) (*citing cases*).

The Examiner argues that "there is a reasonable expectation of success, since both the floss of [Burch] and [Hill] utilize polymer fibers in the form of multiple strands or filaments." Paper 10, page 5, lines 4-5. The Examiner has not explained why the person of ordinary skill in the art would look to the physical form of the polymer, rather than to its chemical structure, in assessing the expectation of success. The person of ordinary skill in the art is aware that, depending in their chemical structure, polymers in the same physical form can have widely varying properties. Fibers of elastomers, for example, stretch under tension and revert to their original length when the tension is released. Fibers of crystalline polymers,

² The Examiner has abandoned his position that nylon is vinyl elastomer by his failure to support. In addition, appellants have made of record excerpts from standard textbooks in organic chemistry that disclose that nylon is a crystalline polymer. Thus, if reasserted, the Examiner's position is entitled to little weight. *In re Wagner*, 152 U.S.P.Q. 552, 559 (CCPA 1967) (factually unsupported opinions of examiners are of little weight against contrary evidence).

such as nylon, do not. The person of ordinary skill of the art would be guided by the chemical structure of the polymer not by its physical form.

The rejection of claims 1-22 and 25-29 as unpatentable over the combination of Burch and Hill should be reversed.

(c) Hill teaches away from absorbing the ingredients in the dental floss

Further, Hill teaches away from imbibing or absorbing the ingredients into the dental floss. Hill teaches that is critical that the loading be accomplished in the interstitial space. In addition, Hill teaches that "impregnation," or absorption of the material into the fiber, is primarily coating.

It is critical for the purpose of the method of the present invention that much of this "loading" be accomplished in the interstitial spaces of the floss as distinguished from simply "coating" the outer surfaces of the bundle of floss strands. Much of what is called "Impregnation": in prior floss art is, upon careful examination, primarily "coating". Thus, the pressures and forces encountered during flossing allow for the loaded material to be progressively released interproximally between the teeth and under the gum line. This "interstitial loading" is particularly critical in order to avoid "stripping" the floss of active ingredients while the floss is being inserted between the teeth and to avoid transferring major quantities of loaded materials to the fingers during flossing.

Hill, column 19, line 39, to column 20, line 11 (emphasis added).

Hill also teaches the advantages of having the having the chemotherapeutic agents in the interstitial spaces of the dental floss. For example, Hill teaches that the chemotherapeutic agents can function as a binder for the strands of the dental floss,

but unlike wax and other binders, they permit the floss to spread out during flossing, so that improved flossing results.

Surprisingly, when the chemotherapeutic agents of the present invention are added to floss strands they perform one critical function of the standard size or binder in that they keep the floss from untwisting during use and impart the "stickiness" necessary to allow the floss to be spooled and dispensed without unraveling. However, because of the chemistry of these substances and the loading process used; contrary to the bonded or waxed floss, the loaded floss of the present invention spreads out during use to obtain the separate mechanical action of the many filaments.

Hill, column 8, lines 6-16 (emphasis added).

Hill further describes how the tendency of the dental floss to open up and flatten out during flossing produces several advantages, such as "to pass easily between teeth which are so closely spaced as to make insertion of typical floss critical and painful." Hill, column 13, line 67, to column 14, line 18.

The person of ordinary skill in the art, wanting to produce an dental floss comprising a chemotherapeutic agent and having the advantage of the teachings of Hill would not be motivated to imbibe or absorb a chemotherapeutic agent into the floss. Hill teaches that it is critical that the chemotherapeutic agent be in the interstitial spaces of the floss and that this produces several advantages, which would be lost if the chemotherapeutic agents were absorbed into the floss. Hill further teaches that materials that are allegedly "impregnated" into dental floss are really just coated on the outer surface of the bundle of fibers. Consequently, Hill teaches away from appellants' invention.

A reference that teaches away from an invention cannot be combined with other references to make it obvious. *In re Grasselli*, 218 U.S.P.Q. 769, 779 (Fed.

Cir. 1983); MPEP 2145. The rejection of claims 1-22 and 25-29 as unpatentable over the combination of Burch and Hill should be reversed.

(d) Summary

The rejection of the Claims of Group I, and well as the rejection of all the other claims on appeal, as unpatentable over Burch in view of Hill should be reversed because the Examiner has not made the *prima facie* case for one or more of the following reasons:

1. Combination of Burch and Hill in the manner indicated does not produce appellants' invention.
2. There is no reasonable expectation of success from the combination of Burch and Hill.
3. Hill teaches away from appellants' invention.

The Claims of Group II

Group II consists of claims 2, 3, and 11. The claims of Group II recite additional limitations for the fiber of the elastomeric polymer. For the reasons given with respect to the claims of Group I, above, the rejection of the claims of Group II should be reversed. However, the rejection of these claims should be reversed for the following additional reason.

Nothing in Burch, or Hill, or the combination thereof suggests that an elastomeric fiber with the recited structure could absorb a therapeutically effective amount of a chemotherapeutic agent. For this additional reason, the rejection of the claims of Group II should be reversed.

The Claims of Group III

Group III consists of claims 4, 20, and 21. The claims of Group III recite additional limitations for the fiber of the elastomeric polymer. For the reasons given

with respect to the claims of Group I, above, the rejection of the claims of Group III should be reversed. However, the rejection of these claims should be reversed for the following additional reason.

Nothing in Burch, or Hill, or the combination thereof suggests that a fiber with the recited combination of denier value, tensile strength, and break elongation could absorb a therapeutically effective amount of a chemotherapeutic agent. For this additional reason, the rejection of the claims of Group III should be reversed.

The Claims of Group IV

Group IV consists of claims 5-9, 12, and 22. The claims of Group IV recite the limitations of the claims of Group II and the claims of Group III. For the reasons given with respect to the claims of Group I, the claims of Group II, and the claims of Group III above, the rejection of the claims of Group IV should be reversed. For the following additional reason, the rejection of the claims of Group IV should be reversed.

Nothing in Burch, or Hill, or the combination thereof discloses or suggests that a fiber with this combination of structure and properties could absorb a therapeutically effective amount of a chemotherapeutic agent. For this additional reason, the rejection of the claims of Group IV should be reversed.

The Claims of Group V

Group V consists of claims 14, 16, 17, and 19. The claims of Group V contain an additional limitation: the fiber comprises at least about 1,000 ppm of water soluble fluoride. For the reasons given with respect to the Claims of Group I, above, the rejection of the claims of Group V should be reversed. However, the rejection of these claims should be reversed for the following additional reason. Appellants' results are unexpected.

Example 1 shows that a spandex fiber takes up 2300 ppm of fluoride.

Comparative Example 1 shows that a conventional dental floss takes up 385 ppm of fluoride. As an additional comparison, as noted in Comparative Example 1, J. Jørgensen, *et al.*, Pediatric Dentistry, 11(1), 17-20 (1989) (of record) report uptakes of 201 ± 19 ppm and 248 ± 17 ppm of fluoride when a conventional dental floss was immersed in fluoride-containing dental products.

Nothing in Burch, Hill, or the combination thereof would lead a person of ordinary skill in the art to believe that at least about 1,000 ppm of water soluble fluoride could be imbibed into an elastomeric fiber.

The Examiner argues “it is unknown whether the ‘conventional dental floss’ compared in Example is the same dental floss as Hill. Therefore, it is unclear whether the spandex dental floss would absorb more fluoride than the dental floss of Hill.” Paper 10, page 6, lines 5-7. The Examiner has not explained why the dental floss of Hill is an appropriate comparison. Hill discloses nothing about absorbing fluoride into dental floss. His invention lies in loading the delivery system into the interstitial spaces between the strands as “substantially aqueous free, hot-melt emulsion.” Hill, column 6, lines 17-57, especially lines 47-48; *see also*, column 29, lines 36-38, Example 62; and claim 1, lines 20-21. There is no evidence that any fluoride was absorbed into the fiber under these conditions. Nor is there any reason for the person of ordinary skill in the art to believe that any of the agent was absorbed by the fiber under these conditions, especially because Hill teaches that much of what is called impregnation is actually coating. Hill, column 20, lines 1-3.

Further, Hill uses a dental floss comprising nylon strands. Hill, column 8, lines 30-33. There is no evidence that the nylon used by Hill differs from the nylon used in other dental floss. Hill, column 12, lines 14-21. In Examples 9-39, for example “white nylon unbonded floss” was used. Hill, column 22, lines 29-31. The appropriate comparison is conventional dental floss.

Appellants have shown that unexpectedly high levels of fluoride can be

incorporated into elastomeric dental floss. The rejection of the claims of Group V should be reversed.

The Claims of Group VI

Group VI consists of claims 13, 15, 18, and 25-29. The claims of Group VI recite that fiber comprises at least about 2,000 ppm of water soluble fluoride. For the reasons given with respect to the Claims of Group I and the claims of Group V, above, the rejection of the claims of Group VI should be reversed.

However, the rejection of these claims should be reversed for the following additional reason: appellants' results are unexpected. Nothing in Burch, or Hill, or the combination thereof would lead a person of ordinary skill in the art to believe that at least about 2,000 ppm of water soluble fluoride could be imbibed into an elastomeric fiber.

Appellants have shown that unexpectedly high levels of fluoride can be incorporated into elastomeric dental floss. The rejection of the claims of Group V should be reversed.

F. Response to the Examiner's "Response to Arguments"

The Examiner raised several issues in the "Response to Arguments." Most of these issues have been addressed in the discussion above. However, two additional issues are addressed below.

1. Appellants have not attached the references individually

The Examiner states that:

Applicants also argue that combination of the references does not produce applicants' invention as Hill allegedly does not teach that chemotherapeutic agents are imbibed within the nylon dental floss.

In response, it is submitted that one cannot show

nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 981); *In re Merck & Co*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Paper 10, page 5, lines 10-16.

Appellants are not, as the Examiner suggests, "attacking references individually." Appellants are attacking the Examiner's combination of references because the combination does not produce the *prima facie* case.

To make the *prima facie* case, the "reference (or references when combined) must teach or suggest all of the claim limitations. MPEP 4142 (case citations omitted) (emphasis added). When, as in this case, the combination does not teach or suggest all of the claim limitations, the Examiner has not made the *prima facie* case and the rejection must be reversed.

Appellants have shown that Hill does not teach or suggest what the Examiner claims it does. Consequently, the combination of Burch and Hill does not "teach or suggest all of the claim limitations" and the rejection must be reversed.

Appellants are entirely within their rights in pointing out that one reference in a combination does not disclose or suggest what an Examiner alleges that it does. To hold otherwise would effectively prevent an applicant from challenging an Examiner's reading of any reference cited as part of a combination of references, no matter what the Examiner alleged the reference disclosed or suggested.

2. The meaning the word "imbibed"

The Examiner states that:

Furthermore, the term "imbibed does not differentiate how the fiber is loaded with the chemotherapeutic agent. "Imbibed" is defined by Merriam-Webster's' Collegiate Dictionary 10th Edition as "to

absorb or assimilate moisture, gas, light or heat." Thus, imbibed does not distinguish how the fiber is loaded with agent, merely that it is loaded with agent.

Page 5, lines 17-21.

Merriam-Webster's' Collegiate Dictionary 10th Edition was newly cited in the first action final rejection following appellants CPA. Paper 10. The reference was not made of record, and appellants were not provided with a copy. Thus, appellants have not been able to fully evaluate the teachings of this reference. For this reason, appellants submit that the Board should not consider this argument, and it is unnecessary for appellants to respond. However, in the interest of completeness, appellants offer the following remarks should the Board decide to consider the Examiner's argument.

The Examiner states that "'imbibed' does not differentiate how the fiber is loaded with the chemotherapeutic agent." Differentiate from what? The Examiner has failed to indicate from what the term "imbibed" fails to distinguish. Presumably, the Examiner is referring to the disclosure of Hill. If so, it appears that the Examiner is attempting to make a rejection under 35 U.S.C. § 102(b), not under 35 U.S.C. § 103(a).

The Examiner alleges that the definition for "imbibed" is "to absorb or assimilate moisture, gas, light, or heat." It is readily apparent that this is not a definition for the adjective "imbibed" but is a definition for a verb, presumably the verb "to imbibe."

Merriam-Webster's' Collegiate Dictionary (7th edition), an earlier edition of the reference relied on by the Examiner, gives the following definition for the verb

"to imbibe":³

imbibe [derivation and pronunciation omitted] *vt* **1. archaic** :
soak, steep **2 a** : to receive into the mind and retain (~ moral
principles) **b** : to assimilate or take into solution **3 a** : drink **b** :
absorb ~ *vi* **1** : drink **2 2 a** : to take in liquid **b** : to absorb or
assimilate moisture, gas, light or heat **syn** see absorb.

Merriam-Webster's' Collegiate Dictionary (7th edition), page 416 (1970) (emphasis added).

Assuming that the 10th edition has essentially the same definition as the 7th edition, the Examiner selectively cited the reference and did not supply appellants with the complete reference so that they could fully evaluate its teachings. In particular, the full definition indicates that "absorb" is a synonym for "imbibe." Consequently, the adjective "imbibed" is a synonym for "absorbed."

Hill discloses dental floss in which "the compositions employed are contained essentially in the interstitial spaces between the fibers of the floss. " Hill, column 13, lines 58-62. In appellants' claims, the chemotherapeutic agent is "imbibed in the fiber." Appellants' claims are clearly distinguished from the disclosure of Hill.

E. Conclusion

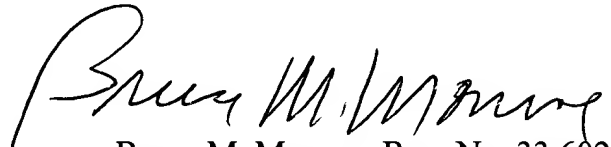
As discussed above, the Examiner has not made the *prima facie* case. Appellants' invention is neither disclosed nor suggested by the applied references. Further, appellants have presented objective evidence of non-obviousness.

³A copy of Merriam-Webster's' Collegiate Dictionary (7th edition), page 416 (1970), is included with this Appeal Brief. If the Board considers the Examiner's argument, the Board is respectfully requested to instruct the examiner to make this reference of record.

BUR-020

The rejection of claims 1-22 and 25-29 under 35 U.S.C. § 103(a) as unpatentable over Burch, U.S. Pat. No. 5,433,266, in view of Hill, U.S. Pat. No. 5,098, 711, should be reversed and such action is earnestly solicited.

Respectfully submitted,



Bruce M. Monroe, Reg. No. 33,602
Attorney for Appellants

Date: *Oct. 8, 2001*

RATNER & PRESTIA
P.O. Box 7228
Wilmington, DE 19803
(302)-479-9470
FAX: (302)-479-9480

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on: *OCT. 8, 2001*

Nancy Stanford

NANCY STANFORD

(9) APPENDIX

CLAIMS ON APPEAL

1. A fiber comprising:
 - (a) a fiber of an elastomeric polymer capable of imbibing a chemotherapeutic agent; and
 - (b) a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber.
2. The fiber of claim 1 in which the fiber has a core of a segmented polymer; the segmented polymer has soft segments and hard segments; the hard segments are selected from the group consisting of urethane, amide, imide, and mixtures thereof; the soft segments are selected from the group consisting of polyester, polyether, and mixtures thereof; and the hard segments are linked to the soft segments by covalent bonds.
3. The fiber of claim 2 in which the chemotherapeutic agent is a substance useful in dental hygiene.
4. The fiber of claim 1 in which the fiber has:
 - a denier value in the range of 40 to 4,000;
 - a tensile strength higher than 0.5 grams per denier; and
 - a break elongation of at least 400%;the fiber requiring a stress to elongate selected from the group consisting of 0.03 to 0.4 grams per denier to develop an elongation of 200% and 0.07 to 0.6 grams per denier to develop an elongation of 300%.
5. The fiber of claim 4 in which the fiber has a core of a segmented polymer; the segmented polymer has soft segments and hard segments; the hard segments are selected from the group consisting of urethane, amide, imide, and mixtures thereof; and the hard segments are linked to the soft segments by covalent

bonds.

6. The fiber of claim 5 in which the chemotherapeutic agent is a substance useful in dental hygiene.

7. The fiber of claim 5 in which the chemotherapeutic agent is selected from the group consisting of sodium fluoride and stannous fluoride.

8. The fiber of claim 5 in which the chemotherapeutic agent is a penicillin.

9. The fiber of claim 5 in which the chemotherapeutic agent is chlorhexidine.

10. An assembly comprising a box and a dental floss at least partially enclosed in said box, the dental floss comprising:

(a) a fiber of an elastomeric polymer capable of imbibing a chemotherapeutic agent; and

(b) a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber.

11. The assembly of claim 10 in which the fiber has a core of a segmented polymer; the segmented polymer has soft segments and hard segments; the hard segments are selected from the group consisting of urethane, amide, imide, and mixtures thereof; the soft segments are selected from the group consisting of polyester, polyether, and mixtures thereof; and the hard segments are linked to the soft segments by covalent bonds.

12. The assembly of claim 11 in which the fiber has:

a denier value in the range of 40 to 4,000;

a tensile strength higher than 0.5 grams per denier; and

a break elongation of at least 400%;

the fiber requiring a stress to elongate selected from the group consisting of

0.03 to 0.4 grams per denier to develop an elongation of 200% and 0.07 to 0.6 grams per denier to develop an elongation of 300%.

13. The assembly of claim 12 in which the fiber comprises at least about 2,000 ppm of water soluble fluoride.

14. A fluoride-containing fiber prepared by adding a fiber to an aqueous solution or dispersion of a fluoride salt for a time sufficient for the fiber to imbibe fluoride;

in which:

the pH of the aqueous solution or dispersion is greater than about 1; and

the fluoride-containing fiber comprises at least about 1,000 ppm of water soluble fluoride.

15. The fluoride-containing fiber of claim 14 in which the fiber comprises at least about 2,000 ppm of water soluble fluoride.

16. The fluoride-containing fiber of claim 14 in which the time sufficient for the fiber to imbibe fluoride is less than twenty four hours.

17. The fluoride-containing fiber of claim 15 in which the fiber has:

a denier value in the range of 40 to 4,000;

a tensile strength higher than 0.5 grams per denier; and

a break elongation of at least 400%;

the fiber requiring a stress to elongate selected from the group consisting of 0.03 to 0.4 grams per denier to develop an elongation of 200% and 0.07 to 0.6 grams per denier to develop an elongation of 300%.

18. The fluoride-containing fiber of claim 17 in which the fiber comprises at least about 2,000 ppm of water soluble fluoride.

19. A method for preparing a fluoride-containing fiber, the method comprising adding a fiber to an aqueous solution or dispersion of a fluoride salt for

a time sufficient for the fiber to imbibe fluoride;

in which:

the pH of the aqueous solution or dispersion is greater than about 1; and

the fluoride-containing fiber comprises at least about 1,000 ppm of water soluble fluoride.

20. A method for preparing an imbibed fiber of an elastomeric polymer capable of imbibing a chemotherapeutic agent comprising a therapeutically effective amount of the chemotherapeutic agent, the method comprising adding a fiber to an aqueous solution or dispersion of a chemotherapeutic agent for a time sufficient for the fiber to imbibe the therapeutically effective amount of the chemotherapeutic agent;

in which:

the fiber has a denier value in the range of 40 to 4,000, a tensile strength higher than 0.5 grams per denier, and a break elongation of at least 400%;

the fiber requires a stress to elongate selected from the group consisting of 0.03 to 0.4 grams per denier to develop an elongation of 200% and 0.07 to 0.6 grams per denier to develop an elongation of 300%.

21. The method of claim 20 in which the aqueous solvent is water.

22. The method of claim 20 in which the fiber has a core of a segmented polymer; the segmented polymer has soft segments and hard segments; the hard segments are selected from the group consisting of urethane, amide, imide, and mixtures thereof; the soft segments are selected from the group consisting of polyester, polyether, and mixtures thereof; and the hard segments are linked to the soft segments by covalent bonds.

25. The fiber of claim 1 in which the fiber comprises at least about 2,000 ppm of water soluble fluoride.

26. The fiber of claim 25 in which the fiber has:

a denier value in the range of 40 to 4,000;
a tensile strength higher than 0.5 grams per denier; and
a break elongation of at least 400%;

the fiber requiring a stress to elongate selected from the group consisting of 0.03 to 0.4 grams per denier to develop an elongation of 200% and 0.07 to 0.6 grams per denier to develop an elongation of 300%

27. The fiber of claim 26 in which the fiber has a core of a segmented polymer; the segmented polymer has soft segments and hard segments; the hard segments are selected from the group consisting of urethane, amide, imide, and mixtures thereof; and the hard segments are linked to the soft segments by covalent bonds.

28. The fiber of claim 27 in which the water soluble fluoride is selected from the group consisting of sodium fluoride and stannous fluoride.

29. The fiber of claim 28 in which the hard segments are urethane.

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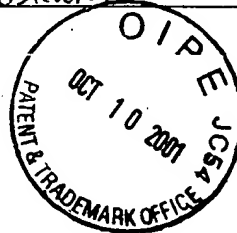
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